16 Feb. 2008

Venturix Thrombectomy Catheter

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NDSU Team

Venturix Thrombectomy Catheter
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Updates, Proposals, and Finances

For the Design of a Thrombectomy Catheter

Abstract: A micro multi lumen catheter for removing thromboemboli or thrombus from cerebral/venous arteries of patients suffering from strokes. The conceived micro catheter provides an extraction lumen which would be capable of sucking the blood clots out from the tiny blood vessels. The catheter will use either RF or Lasers as a power source to test the conceived design. Enova's patented idea on Venturix will be the base of the design. However slight modifications in the design concept would be tested as well to check for the better performance. The catheter system thus provides a functional high pressure extraction lumen which would eventually suck the clot and even break it. Preferred mechanisms for power source to the system are: (i) a CW Diode Laser source and controller coupled to optic fibers in the catheter wall and (ii) a RF source coupled to paired electrodes or carbon fiber within the extraction lumen. Each energy source can generate pulses to break the clot or to create the same effects. The NDSU team is waiting for finances and expects active and immediate initiative from Enova.

Venturix Thrombectomy Catheter with Enova Medical Technologies at NDSU

Design:

There are two separate and very different methods that could be employed to meet the objectives of this catheter. The fist deals with using RF energy to vaporize saline at the distil end of the catheter. The second method deals with working with a laser to achieve the same effect. We will investigate the use of each method, and the requirements of each option will be summarized herein after a short description of how the clot removal process currently works. With the use of RF energy, a current is passed directly between two electrodes through a saline solution. This energy is powerful enough to vaporize the saline in the working end of the catheter. This action causes two things: (i) it acts as a sort of hammering effect on the clot and breaks it up and (ii) it also creates a high pressure flow through the “venturi effect” to help catalyze a flow of the debris out through the catheter. The “venturi effect” is caused by the design of the working end of the catheter. This effect is comparable to forcing a lot of water (except in this case it would be the vapor) through a small hose; there will be high pressure flow.

If we employ the use of RF energy we’ll use a function generator to achieve the proper frequency range. However, the power output won’t be large enough to vaporize the solution. We’ll need to design and build a RF amplifier to achieve the proper power level which currently is in progress. Along with the amplifier, we’ll need a method to control the signal so we can test different energy pulsing methods. Another important factor to take into account is temperature inside the arteries, so we’ll need to build a system that can monitor and display the temperature at and inside the working end. This has already been built and tested successfully.

Power Source: Lasers

The type of laser that we have in mind is a very compact multi-watt CW diode laser. We are trying to figure out its cost, lab facility, laser’s electromagnetic effect on cells and human health, strength of the optical fibers, and elasticity of the fiber.

Properties of Lasers:

A laser beam is an electromagnetic wave that has the property of being strongly guided in a waveguide, such as a silica fiber with 125 um diameter. That confinement is much better than the ones observed in RF signals transmitted through conductive cables.

Several watts of CW power can be transmitted through an optical fiber with negligible leak of radiation through the cladding. That would ensure that the cladding of the fiber is pretty much at room temperature while the several watts of optical power coming out of the fiber end can produce an intense localized heat. To do so, one just needs to terminate

the fiber with a cap (the so called “boot”) that absorbs most of the incoming radiation converting it to heat. In that case the vaporization precludes the need of a conductive saline solution.

The need for temperature control and a method for pulsing will also be needed if we use a laser as the source of vaporization. The method for pulsing will be different in that we aren’t controlling the energy signal directly, but instead of controlling the laser and how often it’s on. We’ll also need to look into the properties of lasers, to determine how to best control the energy produced.

Existing Patent:

The Enova Medical Technologies, which is our sponsoring company for this project has already a patent **(US Patent - US 6,679,879 B2, Jan 20, 2004)** for this technology. But as the need is demanding in the neural market, we are free to look into other possible area to achieve the same goal. So, as we look into the existing patents for the similar technology, what we found is that there are already dominant key players in the coronary and peripheral treatment (although small in numbers) but the neural market is still untouched.

Lasers is also used in the treatment as to burn the plaque (which helps the clot formation) and also to break the thrombus and then extracted by a catheter of choice.

However our approach is unique and we are not interfering any of the existing patent but guided under the venture principle, we are experimenting our own new way to remove the early blood clots completely. As for the laser is concerned, our target is to just vaporize the water to check the strength of our selected laser and if successful then start working on the lasers to vaporize the saline solution and also breaking the clots.

Constraints:

Size: Should be very small (1.25 mm – 4 mm)

Materials: Should be very flexible (catheter and working end)

Outside temperature: Within the limited precise range (< 45 -60 degree C)

Limitations: Financial, possible side-effects, future development, safe, FDA approval, cheaper, better than most of the current day technologies

Updated Project Description:

Concept of Design: Our goal is to remove the blood clots from very thin veins/ arteries to save stroke patients. To accomplish this we are currently working on a catheter project using the venture principle to break and suck the blood clots. There are already many medical companies who do so by their different kinds of catheters and methods. However what was interesting to note was that most of the current day technologies and catheters are not really satisfactory (based upon the numerous factors). The treatment is not very precise and accurate. The treatment safety rate is as low as 47% - 0% depending upon the thrombosis area. The thin veins and arteries are still out of our choice in treatment.

In most of the cases specialist uses blood thinners to help break the clots but according to the researches that have done, it is very harmful for the patient's health. Our goal is to build a catheter as small as 1.10- 1.35 mm (in diameter) to cover the neural thrombosis which is yet untouched by the whole medical industry. We are currently using 'agar" to imitate the blood clots in properties and we are testing the Power Amplifier which we are currently building and testing.

Lasers and Optical Fibers: As it is mentioned before the optical fiber can be the key thing into this research. Since optical fibers are made up of glass materials so the vacuum or the pressure difference can be maintained over the long length. This will solve the problem for the poor suction resulting from the PVC or plastic catheters.

Size and Lasers: The biggest advantage with the Lasers is the size of the optical fiber it will be using. The typical optical fiber which we are considering to use is of 125 μm (micro meter) in diameter. This is extremely small compared to the electrodes and the cu wires in case of the RF. Also since we need only one source of the lasers (unlike two electrode wires in RF), this will eventually reduce the number of desired lumens in the catheter.

RF Generator:

Dr. Schroeder talked with Michael Hoey, the CTO of the company and he was informed that there is one spare RF generator at Enova which we can use for our initial testing and for comparing the Power Amplifier which we are making at NDSU.

Proposals and Finances:

As the project is in its 5th month of progress and we have moved quite a bit ahead of the design procedure and planning. We are currently using the lab facilities of the Photonics Lab (for Lasers) and the Electrical/ Electronic Lab of the NDSU for the design. We are also accessing the resources of the Industrial and Manufacturing tool shop of the IME department. However we are getting slowed down on the scarcity of the funds and necessary equipments.

In our current situation we immediately need a drill machine of 500 µm diameter. We also need to buy the coating for the optical fibers, optical fiber catheters for testing the vacuum/ suction effect.

The Lasers we are currently using is a 7W and 5W CW Diode lasers and we probably will need a higher wattage (40W) lasers for the future testing. It might seem that the lasers is extra costing on the project but then the results it promises in terms of size of the catheter can not be neglected. In fact I would say we must give lasers a chance and we will reach our goal of 1.35 mm catheter.

Anticipated Budget:

Item	**Cost**	**Immediate Requirement**
Drilling materials and equipments (one time set-up and costing)	$500	Yes
Water pump, RF, Test Set –up; Miscellaneous	$500	Yes
Lasers (one time set-up and costing)	$700	--
Catheter manufacturing/ buying	$500	--

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